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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,535	10/03/2003	Janmarie Hornack	30900-CNT2	3990

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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9d.

Office Action Summary	**Application No.** 10/679,535	**Applicant(s)** HORNACK ET AL.
	Examiner Ruth A. Davis	**Art Unit** 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.
4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-10* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date *3-04*.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1 – 10 in the reply filed on July 22, 2004 is acknowledged. The traversal is on the grounds that the reasons of distinctness are in error since the claimed method occurs in the stomach, not the intestine as exemplified by the examiner. This is not found persuasive because as stated in the previous office action, other materially different products could certainly improve availability of supplements such as lactobacillus. While the modes of operation may be different than the instant claims, the method of improving bioavailability of supplements is the same. Furthermore, it is reiterated that a reference that would anticipate one invention would not necessarily anticipate or even make obvious the other.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11 – 13 are withdrawn from further consideration as being drawn to non-elected subject matter. Claims 1 – 10 have been considered on the merits.

Claim Objections

2. Claim 9 is objected to because of the following informalities:

The term "pyroxdine" should be spelled correctly as "pyridoxine". Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1 – 3 are rejected under 35 U.S.C. 102(b)/103 as being anticipated by or obvious over Ehrenpreis et al. (US 4579843).

Applicant claims a composition consisting essentially of a supplemental agent and an electrolyte selected from calcium, magnesium and potassium; wherein the agent is pH 6 or less and wherein the electrolyte raises the pH to about 8 – 12.5, or about 8 – 10.5 such that the effectiveness of the agent is increased in the stomach. The electrolyte is selected from hydroxides, chlorides, chelates, di-phosphates, oxides, stearates, carbonates, gluconates, bicarbonates, phosphates, and sulfates.

Ehrenpreis teaches compositions for treating arthritis and pain, the compositions comprising 100 – 750mg dl-phenylalanine and magnesium stearate (col.2, line 35-45, col.8 line 15-65, claims).

Although the reference does not teach that the agent (dl-phenylalanine) has a pH of 6 or less and has limited availability, or that wherein the magnesium raises the stomach pH for improved effectiveness in the manner claimed, the composition of Ehrenpreis clearly contains the same components of the claimed invention. As such the claimed functional attributes would be inherent to the reference composition. Since the claims do not recite a particular "effective amount", and it is noted that the amounts in the reference composition overlap those disclosed by applicant, it would appear that the reference composition must also function in the manner instantly claimed. However, even if the amounts are not exactly the same, it would have been obvious to one of ordinary skill in the art to adjust the amounts of each ingredient as a matter of routine experimentation, resulting in compositions that would also appear to exhibit the claimed functional characteristics.

Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

6. Claims 1 – 3 are rejected under 35 U.S.C. 102(e)/103 as being anticipated by or obvious over Kirschner et al (US 6261600 B1).

Applicant claims a composition consisting essentially of a supplemental agent and an electrolyte selected from calcium, magnesium and potassium; wherein the agent is pH 6 or less and wherein the electrolyte raises the pH to about 8 – 12.5, or about 8 – 10.5 such that the effectiveness of the agent is increased in the stomach. The electrolyte is selected from hydroxides, chlorides, chelates, di-phosphates, oxides, stearates, carbonates, gluconates, bicarbonates, phosphates, and sulfates.

Kirschner teaches compositions comprising folic acid (water soluble vitamin) and calcium, magnesium or potassium (col.4 line 40-44). Specifically, the compounds may be calcium carbonate, calcium hydroxide, calcium phosphate, magnesium carbonate, magnesium hydroxide, magnesium oxide, potassium carbonate, potassium phosphate or mixtures thereof (col.7 line 35-59).

Although the reference does not teach that the agent (folic acid) has a pH of 6 or less and has limited availability, or that wherein the electrolytes raise the stomach pH for improved effectiveness in the manner claimed, the composition of Kirschner clearly contains the same components of the claimed invention. As such the claimed functional attributes would be inherent to the reference composition. Since the claims do not recite a particular "effective amount", and it is noted that the amounts in the reference composition overlap those disclosed by applicant, it would appear that the reference composition must also function in the manner instantly claimed. However, even if the amounts are not exactly the same, it would have been obvious to one of ordinary skill in the art to adjust the amounts of each ingredient as a matter of routine experimentation, resulting in compositions that would also appear to exhibit the claimed functional characteristics.

Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

7. Claims 1 – 4 are rejected under 35 U.S.C. 102(e)/103 as being anticipated by or obvious over Sorgente et al. (US 6126787 A).

Applicant claims a composition consisting essentially of a supplemental agent and an electrolyte selected from calcium, magnesium and potassium; wherein the agent is pH 6 or less and wherein the electrolyte raises the pH to about 8 – 12.5, or about 8 – 10.5 such that the effectiveness of the agent is increased in the stomach. The electrolyte is selected from hydroxides, chlorides, chelates, di-phosphates, oxides, stearates, carbonates, gluconates, bicarbonates, phosphates, and sulfates and the agent is glucosamine.

Sorgente teaches compositions for treating arthritis and osteoarthritis, the composition comprising 50 – 1000mg glucosamine, 1 – 500mg ascorbic acid (col.4 line 47-63), 0.1 – 10mg magnesium (col.5 line 10-15). Specifically, glucosamine sulfate and magnesium phosphate (examples).

Although the reference does not teach that the agents (glucosamine, ascorbic acid) have a pH of 6 or less and has limited availability, or that wherein the electrolytes raise the stomach pH for improved effectiveness in the manner claimed, the composition of Sorgente clearly contains the same components of the claimed invention. As such the claimed functional attributes would be inherent to the reference composition. Since the claims do not recite a particular "effective amount", and it is noted that the amounts in the reference composition overlap those disclosed by applicant, it would appear that the reference composition must also function in the manner instantly claimed. However, even if the amounts are not exactly the same, it would have been obvious to one of ordinary skill in the art to adjust the amounts of each ingredient as a matter of routine experimentation, resulting in compositions that would also appear to exhibit the claimed functional characteristics.

Please note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C 102 and 103 (MPEP 2112).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 – 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (US 6346519 B1) or Phillips (US 2003/0180389 A1).

Applicant claims a composition consisting essentially of a supplemental agent and an electrolyte selected from calcium, magnesium and potassium; wherein the agent is pH 6 or less and wherein the electrolyte raises the pH to about 8 – 12.5 or about 8 – 10.5, such that the effectiveness of the agent is increased in the stomach. The electrolyte is selected from hydroxides, chlorides, chelates, di-phosphates, oxides, stearates, carbonates, gluconates, bicarbonates, phosphates, and sulfates; and the agent is glucosamine; glucosamine and MSM; MSM; or MSM and ascorbic acid.

Petrus teaches compositions for treating joint pain comprising 500mg glucosamine sulfate (col.4 line 36-62), vitamin C (ascorbic acid), magnesium, and MSM (col.7 line 52-62).

Phillips teaches compositions for treating joint pain comprising glucosamine, potassium chloride (0026,0027), MSM (0030), ascorbic acid (0032), potassium bicarbonate (0033) and calcium carbonate (example).

The references do not teach the compositions wherein each of the types of electrolytes are used. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to use the claimed electrolytes of calcium, potassium and/or magnesium since they were well known in the art for the same purpose, and because they were routinely interchanged in the art. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine experimentation to substitute any of the claimed electrolytes in the reference compositions, with a reasonable expectation for successfully obtaining compositions for treating joint pain.

Although the references do not teach that the agents have a pH of 6 or less with limited availability, or that wherein the electrolytes raise the stomach pH for improved effectiveness in the manner claimed, the compositions of Petrus and Phillips clearly contains the same components of the claimed invention. As such the claimed functional attributes would be inherent to the reference composition. Since the claims do not recite a particular "effective amount", and it is noted that the amounts in the reference composition overlap those disclosed by applicant, it would appear that the reference composition must also function in the manner instantly claimed. However, even if the amounts are not exactly the same, it would have been obvious to one of ordinary skill in the art to adjust the amounts of each ingredient as a matter of routine experimentation, resulting in compositions that would also appear to exhibit the claimed functional characteristics.

11. Claims 1 – 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herschler (US 4568547).

Applicant claims a composition comprising a supplemental agent and an electrolyte selected from calcium, magnesium and potassium; wherein the agent is pH 6 or less and wherein the electrolyte raises the pH to about 8 – 12.5 or about 8 – 10.5, such that the effectiveness of the agent is increased in the stomach. The electrolyte is selected from hydroxides, chlorides, chelates, di-phosphates, oxides, stearates, carbonates, gluconates, bicarbonates, phosphates, and sulfates; and the agent is glucosamine; glucosamine and MSM; MSM; MSM and ascorbic acid;

or bioflavonoids and MSM. Specifically, the composition consists essentially of 1000mg MSM, 780mg ascorbic acid, 20mg bioflavonoids, 100mg calcium carbonate, 50mg potassium gluconate, 50mg magnesium oxide.

Herschler teaches compositions comprising MSM, ascorbic acid, bioflavonoids, magnesium, calcium, magnesium oxide, potassium bicarbonate, vitamin B6 (pyridoxine hydrochloride) (examples).

Herschler does not teach the compositions comprising the claimed amounts of each ingredient, or wherein each type of electrolytes are used. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize the amounts of effective ingredients as a matter of routine experimentation. In addition, it would have been obvious to one of ordinary skill in the art to use the claimed electrolytes of calcium, potassium and/or magnesium since they were well known in the art for the same purpose, and because they were routinely interchanged in the art. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine experimentation to optimize the amounts of ingredients and substitute any of the claimed electrolytes in the reference compositions, with a reasonable expectation for successfully obtaining the compositions of Herschler.

Although the reference does not teach that the agents have a pH of 6 or less with limited availability, or that wherein the electrolytes raise the stomach pH for improved effectiveness in the manner claimed, the compositions of Herschler clearly contains the same components of the claimed invention. As such the claimed functional attributes would be inherent to the reference composition. Since the claims do not recite a particular "effective amount", and it is noted that the amounts in the reference composition overlap those disclosed by applicant, it would appear that the reference composition must also function in the manner instantly claimed. However, even if the amounts are not exactly the same, it would have been obvious to one of ordinary skill in the art to adjust the amounts of each ingredient as a matter of routine experimentation, resulting in compositions that would also appear to exhibit the claimed functional characteristics.

12. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips, Ehrenpreis, Weisman (US 5888514 A) and Hastings (US 6224871 B1).

Applicant claims a composition consisting essentially of a supplemental agent and an electrolyte selected from calcium, magnesium and potassium; wherein the agent is pH 6 or less and wherein the electrolyte raises the pH to about 8 – 12.5 such that the effectiveness of the agent is increased in the stomach. Specifically, the composition consists essentially of 500mg glucosamine sulfate, 900mg MSM, 20mg 20% Boswellia extract, 100mg di-phenylalanine, 60mg ascorbic acid, 5mg magnesium carbonate, 50mg potassium carbonate, 100mg calcium gluconate, 10mg ginseng, 10mg 24% ginkgo biloba, 15mg pyridoxine hydrochloride (B6), and 180mg 10% gla borage powder extract.

Phillips teaches composition for treating joint pain and arthritis, the compositions comprising glucosamine, potassium chloride (0026,0027), MSM (0030), ascorbic acid (0032), potassium bicarbonate (0033) and calcium carbonate (example).

Ehrenpreis teaches compositions for treating arthritis and pain, the compositions comprising 100 – 750mg dl-phenylalanine and magnesium stearate (col.2, line 35-45, col.8 line 15-65, claims).

Weisman teaches a composition for treating joint inflammation, the composition comprising 1000mg glucosamine sulfate, 470mg Boswellia, 3500mg ascorbic acid, 120mg pyridoxine hydrochloride (abstract) and 150mg panax (ginseng) (col.1 line 47-61, col.3-4).

Hastings teaches composition for treating joint pain, the compositions comprising glucosamine sulfate, ginkgo biloba, borage powder and boswellia (abstract, col.1 line 60-col.2 line 10, examples).

The above references do not teach the compositions comprising each of the claimed ingredients together in a single composition at the claimed amounts. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for the same purpose of treating joint pain. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant components together with a reasonable expectation for successfully obtaining a composition for treating joint pain. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518.

Although the references do not teach that the agents have a pH of 6 or less with limited availability, or that wherein the electrolytes raise the stomach pH for improved effectiveness in the manner claimed, the compositions of the cited references clearly contains the same components of the claimed invention. As such the claimed functional attributes would be inherent to the composition obtained by the combine teachings. It is noted that the amounts in the reference composition overlap those disclosed by applicant, thus it would appear that the reference composition must also function in the manner instantly claimed. However, even if the amounts are not exactly the same, it would have been obvious to one of ordinary skill in the art to adjust the amounts of each ingredient as a matter of routine experimentation, resulting in compositions that would also appear to exhibit the claimed functional characteristics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis; rad
August 6, 2004.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER